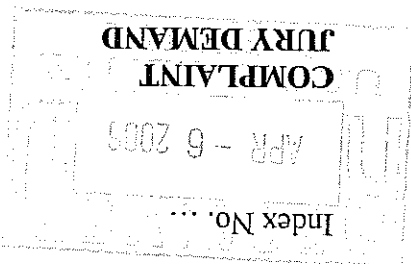


1. This is an action for money damages and other relief by Plaintiff FERNANDO PORTES against DEFENDANTS WYETH PHARMACEUTICALS, INC. ("WYETH"), and Individual Defendants MAURA CORCORAN, JEFF HUTT and CYBIL ROBBINS, officials responsible for the actions giving rise to this complaint, in their individual capacities.
2. Plaintiff's claims are based upon violations of the employee protection provision of the Sarbanes-Oxley Act of 2002, 18 USC 1514A.
3. Plaintiff seeks reinstatement, back pay, compensatory damages, special damages and other relief based upon personnel actions taken against Plaintiff while he was employed at WYETH's Pearl River facility.

## INTRODUCTION

FERNANDO PORTES,  
Plaintiff,  
v.  
WYETH PHARMACEUTICALS, INC.,  
MAURA CORCORAN, JEFF HUTT and  
CYBIL ROBBINS,  
Defendants.



4. Plaintiff was terminated from his employment in retaliation for protected disclosures of fraudulent reporting and lack of compliance with regulations pertaining to the manufacture of vaccines and pharmaceuticals.
5. This Court has jurisdiction, pursuant to 28 U.S.C. § 1331, since this matter is founded on the existence of a federal question. The action arises under the Sarbanes-Oxley Act of 2002, 18 USC 1514A(a)(1).
6. The Secretary of Labor took no action in this matter after 180 days of a timely filing pursuant to 18 U.S.C. § 1514A(b)(1)(B), and issued a determination on October 26, 2005 granting Plaintiff the right to seek relief before this Court.
7. Venue lies in this judicial district pursuant to 28 USC § 1391(b) since the transactions and occurrences which give rise to this complaint occurred in the Pearl River facility, which is located within the jurisdiction of this court.
8. Plaintiff FERNANDO PORTES is a resident of the State of New Jersey and a citizen of the United States.
9. Defendant WYETH is a publicly traded Delaware corporation that engages in the research, development, manufacture, distribution and sale of a diversified line of pharmaceutical and healthcare products.
10. Defendant WYETH has manufacturing facilities in Pearl River that manufactures vaccines and pharmaceuticals, including Prevnar, one of the world's highest selling vaccines. ("Pearl River.")

## **PARTIES**

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## **JURISDICTION AND VENUE**

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- device industries, 14 years of which is work as a project manager leading teams of
19. Plaintiff has over 17 years of work experience in the pharmaceutical and medical Dominican Chemical Society.
18. Plaintiff's chemistry thesis was awarded the highest honor in 1986 by the University, Dominican Republic.
- degrees from Cornell University and a Masters in Business Administration from Catholic
17. Plaintiff also has Masters in Engineering and Masters of Professional Studies
16. Plaintiff graduated first in his class.
- oldest university in the Americas.
- in Science ("Magna Cum Laude") degrees from the University of Santo Domingo, the
15. Plaintiff has a Bachelors in Engineering ("Magna Cum Laude") and a Bachelors substantial relevant work experience.
14. Plaintiff is a highly qualified chemical engineer, chemist, and manager, with

### **PLAINTIFF'S EMPLOYMENT AND WORK HISTORY**

- supervised by Defendant Corcoran.
- Sustainable Compliance Initiative (hereinafter "SCI") group. Robbins reported to and was
13. Defendant CYBIL ROBBINS was, at all relevant times, head of WYETH's terms and conditions of plaintiff's employment at WYETH.
- of Quality, who reported to Defendant Hutt, and had authority for all actions affecting the
12. Defendant MAURA CORCORAN was at all relevant times WYETH's Director plaintiff's employment at WYETH.
- Quality and the final authority for all actions affecting the terms and conditions of
11. Defendant JEFF HUTT was at all relevant times WYETH's Vice President of

- engineers, scientist, managers, directors and technicians.
20. Plaintiff holds the certifications of Project Management Professional ("PMP") and Certified Quality Engineer ("CQE").
21. Plaintiff is listed in Who's Who of Science and Engineering.
22. Plaintiff is currently an Affiliate Professor at the Howe School of Technology Management of Stevens Institute of Technology, New Jersey, where he teaches graduate level project management.
23. The Howe School is the largest School of Technology Management in the US, and is ranked in the top five.
- THE 2000 FDA CONSENT DECREE AND WYETH'S DISCLOSURES TO SHAREHOLDERS AND FEDERAL REGULATORS.**
24. In 2000, the Food and Drug Administration (FDA) issued to WYETH a Consent Decree of Condemnation and Permanent Injunction ("the Consent Decree") because of WYETH's repeated violations of Federal quality regulations.
25. The FDA issued the Consent Decree after it found WYETH to be in serious violation of many Federal regulations pertaining to good manufacturing practices for drugs and for selling adulterated drugs.
26. The FDA had seized many WYETH products that were "adulterated" within the meaning of 21 USC § 351(a)(2)(B).
27. Good Manufacturing Practices ("GMPs") are Federal regulations for all manufacturers of pharmaceutical and biological products within the United States and are codified within 21 CFR Parts 210, 211, and 600, respectively.
28. Part 210 pertains to the manufacture, processing, packing and holding of drugs; Part 211 regulates the manufacturing of "finished pharmaceuticals", and Part 600

- regulates the manufacture and production of "biological products."
29. The Consent Decree and the FDA's seizures were based on the FDA's identification of repetitive violations of GMP manufacturing and quality assurance regulations by WYETH at its Pearl River and Marietta, Pennsylvania manufacturing sites.
30. Paragraph 30 of the Consent Decree permanently enjoined WYETH from "directly or indirectly causing to be introduced or delivered into interstate commerce any drug or biological product that is adulterated within the meaning of 21 USC 351 (1)(2)(B) or from causing the adulteration of any drug or biological product while such drug or biological product is held for sale after shipment of one or more of its components in interstate commerce."
31. The Consent Decree also permanently enjoined Defendant WYETH and its agents from introducing "adulterated" drugs or biological products, within the meaning of 21 USC § 351 (a)(2)(B), into interstate commerce.
32. As a result of the Consent Decree, WYETH agreed to disgorge \$30 million of profits in connection with these violations.
33. The FDA inspects hundreds of pharmaceutical facilities every year and consent decrees are issued only to those companies that repeatedly commit the most serious violations of Federal regulations.
34. Between 1994 and 2004 the FDA issued only sixteen consent decrees to pharmaceutical companies.
35. WYETH communicated in 2000 to all employees in its various facilities, including the Pearl River Facility, that it would incorporate Consent Decree mandates

into a company-wide GMP/quality systems improvement process called SCI – Sustainable Compliance Initiative - and that all operations within the WYETH supply chain were to be brought under Consent Decree mandates

36. In Annual Reports for the years 2001 and 2002, WYETH publicly reported to shareholders, FDA regulators, and government securities regulators the \$30 million fine, the financial interest WYETH shareholders had in meeting quality and sustainable compliance mandates in the Consent Decree, and its commitment that “quality and sustainable compliance will continue to be the highest priorities for WYETH in the years ahead.”

37. Non-compliance with the Consent Decree mandates would negatively impact shareholder value, including the fact that WYETH faced fines of \$15,000 per day for missed commitments under the Consent Decree, and also continued negative publicity and others sanctions for continued violations such as higher fines, and even facility closure.

38. For example, the pharmaceutical company, Schering-Plough, was fined 500 million dollars for violating GMPs, as part of a consent decree, and the regulators closed some of Schering-Plough’s manufacturing facilities until all GMP violations were corrected.

39. The fine imposed on Schering-Plough obviously greatly damaged its shareholders and shareholder stock value.

40. WYETH informed compliance-related officers, managers, and employees, including Plaintiff, of these negative repercussions for non-compliance with the Consent Decree on shareholder value.

41. In its 2002 Annual Report to shareholders, WYETH represented that its "number one operating objective" was to "make sure that our manufacturing and operations maintain high quality standards."
42. WYETH further reported that in order to ensure "compliance with Good Manufacturing Practices" and the Consent Decree, it was engaging in a Company wide initiative aimed at strengthening compliance by "taking a more focused and rigorous approach to the creation of robust procedures and systems across our global supply chain and distribution network."
43. It added that, "quality and sustainable compliance will continue to be the highest priorities for WYETH in the years ahead."
44. In its 2005 financial report to shareholders, WYETH stated: "as provided in the consent decree, an expert consultant has conducted a comprehensive inspection of the Marietta and Pearl River facilities and the Company has identified various actions to address the consultant's observations. The Company has completed these actions as to the Marietta facility and has obtained certification of such completion by the expert consultant. As to the Pearl River facility, the Company is in an ongoing process of completing these actions and obtaining verification of the Company's actions. The verification process is subject to review by the FDA."
- PLAINTIFF'S DUTIES AND HIGH QUALIFICATIONS AND WORK PERFORMANCE**
45. Plaintiff was hired by Defendant Corcoran and Cybil Robbins on September 22, 2003.
46. Plaintiff was assigned to the Sustainable Compliance Initiative (hereinafter "SCI") Department as a Principal Project Manager.

47. As Principal Project Manager, Plaintiff's chief responsibilities included ensuring that WYETH complied with Federal drug manufacturing regulations and the mandates of the Consent Decree.

48. As such, Plaintiff's chief responsibility was to highlight and report violations of Federal regulations (GMPs).

49. Plaintiff's direct supervisor at all relevant times was Cybil Robbins, SCI Department's Manager.

50. Robbins reported to Defendant Corcoran.

51. One of Plaintiff's most important responsibilities was leading teams of scientists, engineers and technicians in developing standard operating procedures to ensure that all of WYETH's products comply with the FDA's regulations.

52. In devising operating procedures, Plaintiff relied on and implemented WYETH's own conformance standards.

53. The conformance standards are promulgated by WYETH to ensure that its drug products comply with mandatory Federal regulations and the regulations of countries all over the world where WYETH markets its drugs, including the European Union, Japan, Canada and Australia.

54. As a SCI Principal Project Manager, Plaintiff had the responsibility to attest, by his signature, to WYETH's compliance with GMPs and Federal Law.

55. Thus, Plaintiff's job responsibilities had direct implications for WYETH's reporting requirements under SOX.

56. In addition, Plaintiff was potentially subject to criminal sanction for any violation of federal laws, codified under the Federal Food, Drug, and Cosmetic Act or 21 U.S.C.



§331(a), that prohibit the distribution of adulterated or misbranded drugs in interstate

commerce.

57. Based on Plaintiff's representations, and those of his fellow Project Managers, it was Corcoran's ultimate responsibility to verify WYETH's compliance with Federal regulations under the Sustainable Compliance Initiative timetable provided by the

Consent Decree.

58. Without Corcoran's verification, WYETH faced sanctions under the FDA Consent Decree in the amount of \$15,000 per day, additional fines, and more drastic

action as facility closures, which would have had a negative impact on shareholder value. 59. Plaintiff was eminently qualified for the position of Principal Project Manager for WYETH, a position he occupied until his unlawful discharge on February 23, 2005.

60. Plaintiff's work performance was excellent throughout his employment, as

attested to, in part, by the commendations and bonuses that Plaintiff received.

61. For his first three month review in December 2003, Plaintiff was rated as having "met all expectations" and he was given a year-end prorated bonus.

62. Plaintiff's performance between January 2004 and June 2004 was rated as having "exceeded expectations."

63. In addition, WYETH gave Plaintiff 1200 stock options in May 2004 despite the fact that stock options were not indicated as being part of Plaintiff's compensation.

64. WYETH only grants stock options to individuals with well above average and outstanding performance.

65. Upon information and belief, Plaintiff was the only project manager within his department to have been granted stock options at this time.

66. In 2004, Plaintiff received four unsolicited emails from clients and peers, which praised Plaintiff's management of their projects.

67. Defendant Corcoran informed Plaintiff that the Director of Technical Services and several clients of the SCI department had requested Plaintiff's assignment to their own projects because they were impressed with Plaintiff's work.

68. Between September 2003 and February 2005, there were a total of 11 Project Managers in the SCI Department, including Plaintiff.

69. Plaintiff's background and qualifications were far superior to his peers and to his supervisor, Robbins.

70. All other SCI project managers as well as Plaintiff's supervisor, Robbins, were level 12 or below.

71. Plaintiff was level 13, a higher level of responsibility and salary.

**ROBBINS WAS NOT QUALIFIED TO BE THE SCI HEAD OR PERFORM COMPLIANCE WORK, WHICH IS A VIOLATION OF THE CONSENT DECREE AND FEDERAL REGULATIONS**

72. At all relevant times, WYETH maintained other comparable facilities to those at Pearl River Vaccine Manufacturing, where Plaintiff worked: Sanford, North Carolina; Marietta, Pennsylvania; Andover, Massachusetts; Pearl River Chemical Development; and Pearl River Vaccines Development.

73. Five other individuals at these five other comparable WYETH facilities occupying an equivalent position to that of Robbins, namely a SCI Head, were all at Level 14 (Associate Director-level) or Level 15 (Director-level).

74. Robbins' experience and education did not meet WYETH's requirements for the position she was occupying, which violated the Section 23.A.3 of the Consent Decree,

- which provides that the qualifications of Pearl River personnel must be "adequate in number and qualifications (education, training, and experience, or a combination thereof)".
75. Robbins inexperience and lack of expertise also violated 21 CFR 211.25(a), which provides that: "Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions."
76. Robbins has only a Bachelors of Science degree in Chemical Engineering, no Lab Operations experience, and limited technical skills.
77. Robbins should not have been responsible for managing projects for which she lacked the requisite technical skills and experience, in particular within a facilities that were subject to the stringent terms of an FDA-issued Consent Decree.
78. Robbins was not qualified to occupy the position of SCI Head, and this violated WYETH's own standards, the Consent Decree and Federal regulation 21 CFR 211.25(a).
79. Therefore, Robbins should have never been made the head of the SCI department and permitted to manage the implementation of the Lab Operations conformance standards.
80. In fact, under Robbins' direction, the SCI Department's project managers missed dozens of deadlines in all the other areas during her tenure from 2002 through 2005.
81. During an inspection in December 2003, the FDA issued WYETH's Pearl River Facility with 59 observations for violating US Federal regulations despite the Consent Decree issued three years earlier.
82. Upon information and belief, because of these deficiencies and because of

WYETH's slow progress under the Consent Decree, the FDA threatened WYETH with even more drastic regulatory actions such as facility closure, having concluded that WYETH had not made enough progress under the 2000 Consent Decree.

83. In addition, in or about August 2004, the European Medicines Agency ("EMA"), the European Union's equivalent of the FDA, threatened to pull the sale of Prevnar from Europe - with one billion dollars per year in worldwide sales - unless WYETH brought its quality practices in line with EU standards.

84. Plaintiff's co-workers in the SCI Department had missed many important deadlines when implementing conformance standards.

85. Robbins, and two other Project Managers from the SCI Department, Samantha Santoro and Donna Butler, had formerly managed the implementation of the Lab Operations conformance standards, but had consistently missed numerous deadlines.

86. The mere fact that Robbins was in charge of these important tasks, was not only detrimental to WYETH's compliance efforts under the Consent Decree, it involved a violation of the WYETH's reporting obligations under SOX.

87. Of all WYETH's facilities, WYETH Vaccines Pearl River (where Robbins and Plaintiff worked) was the most critical to meet the requirements of the Consent Decree and to ensure that WYETH complied with Federal regulations (21 CFR 210, 211, and 600), because this facility is the only still existing facility to have been implicated by the Consent Decree.

88. The only other facility that was affected by the Consent Decree, namely the Marietta, Pennsylvania facility, was closed in 2004.

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<sup>1</sup> The Barr Mandate arose out of a lawsuit by the FDA against Barr Laboratories for non compliance with GMPs (USA versus Barr Laboratories, Civil Action No. 92-1744). The Barr Mandate clarified the prohibition against averaging test data in drug manufacture, stating in Paragraph 48: "Although averaging test data can be a rational and valid approach, as a general rule, firms should avoid this practice, because averages hide the variability among individual test results."

95. Plaintiff found serious violations of this Barr Mandate, that Robbins had recognized as being of general application within the drug industry.<sup>1</sup>

averaging test data" as contained or clarified by the dictates of the Barr Mandate that is 600 - and EU regulations, and also contravened the absolute prohibition against "non-were violating the Consent Decree, Federal regulations – namely 21 CFR, 210, 211, and compliance deficiencies, it became apparent to Plaintiff that WYETH's Lab Operations 94. Once given the task of reviewing Robbins' work, which revealed the extensive

**WYETH FACED WITH FURTHER ENFORCEMENT ACTION DUE TO ITS  
NON-COMPLIANCE WITH THE CONSENT DECREE AND  
FEDERAL AND EU REGULATIONS**

implementation.

93. Plaintiff was, however, given impossible deadlines to complete the standards, and because Plaintiff had not missed a single deadline.

including his lead in implementing the Validation and Manufacturing conformance 92. Plaintiff was given this additional responsibility because of his excellent work, asked to lead a non compliant and technically deficient project.

91. Thus Plaintiff's responsibilities as a compliance officer increased and he was implementing the Lab Operations conformance standards.

90. Around June 2004 Defendants assigned Plaintiff the task of leading teams in 89. The WYETH Lab Operations area tests all vaccines manufactured by WYETH.

**PLAINTIFF ASSIGNED HEIGHTENED RESPONSIBILITIES  
REGARDING THE CONFORMANCE STANDARDS**

completely overlooked.

**PLAINTIFF'S FIRST PROTECTED DISCLOSURE**

96. Given the sheer extent of the GMP violations Plaintiff found in Robbins' work, and the elementary nature of these mistakes, Plaintiff justifiably thought that WYETH was violating the Consent Decree and Federal manufacturing regulations generally.

97. In view of the serious consequences that would befall WYETH for these violations, arising from further enforcement action up to and including taking WYETH's drugs off the market, and the ensuing damage to shareholder value, Plaintiff highlighted these conformance violations with his superiors.

98. Plaintiff's responsibilities as SCI Project Manager required the repeated disclosure to management of GMP violations and noncompliant work practices.

99. In or about June 2004, Plaintiff sent Corcoran an email that highlighted the serious violations of the drug regulations that he had discovered.

100. Plaintiff communicated to Corcoran the violations he had discovered, including the following:

a) That most of the Lab Operations conformance standards project Robbins had transferred to plaintiff had violations of 21 CFR 210, 211, and 600, the Barr Mandate, the Consent Decree, and EU regulations, and that they must be corrected; and

b) That Robbins was not qualified to lead the implementation of the Lab Operations conformance standards because she was not a chemist and had never worked in a laboratory.

101. Plaintiff also informed management that he was very confident that he could correct the GMP violations, but that given the sheer extent of the violations that he had

discovered, he needed more time to do so.

102. In addition, in this June 2004 email, Plaintiff communicated to Corcoran that Robbins, who was not qualified to perform the work she was doing, had made far more mistakes in implementing the Lab Operations conformance standards than any other project manager.

103. Plaintiff found in reviewing Robbins' work that she had authorized and verified a vast number of SOPs to be in conformity with the GMPs and the Consent Decree, when in fact they were in violation.

104. Plaintiff compiled and attached to his email a spreadsheet that highlighted in red the extensive violations that Robbins had overlooked, that established that Robbins had overlooked even the most glaring violations.

105. Plaintiff did so to support the fact that Robbins was completely unqualified and to alert his supervisors and managers to the fact that WYETH was manufacturing adulterated drugs.

106. Plaintiff's belief that WYETH was violating Federal Law was based partly on the sheer extent of violations that Plaintiff discovered, and thus Plaintiff reasonably suspected that Robbins had drafted and verified that many SOPs were in conformity with Federal regulations, when, in fact, they were not.

107. Thus, and as a result of the glaring violations uncovered by Plaintiff, it was highly probable that through Robbins' actions, WYETH was violating Federal laws, the Consent Decree, the Barr Mandate, and ultimately, the Sarbanes Oxley Act.

108. Plaintiff's disclosures to Defendants highlighted the fact that WYETH was probably manufacturing adulterated drugs that violated Federal law.

109. Apprized of this information regarding Robbins and the violations, WYETH was obligated to review all SOPs issued by Robbins, in order to assess whether they were in conformity with the GMPs.

110. Upon information and belief, WYETH did not perform such an investigation.

111. On the contrary, and as stated below, WYETH retaliated against Plaintiff, and attempted to impede Plaintiff's attempts to correct the violations he had uncovered.

112. For example, within days of receiving Plaintiff's June 2004 email, and attached spreadsheet, Corcoran called Plaintiff to a meeting at her office, unjustly berated him for sending this email, and did not respond to Plaintiff's requests for an extension of the deadlines.

113. Corcoran told Plaintiff that the email was "totally inappropriate" and that he should not have sent it.

114. Subsequently, via email and in person, Plaintiff requested short extensions of intermediary deadlines to implement the Lab Operations conformance standards at least another four times, but neither Corcoran nor Robbins ever responded.

115. In these communications, Plaintiff again highlighted the serious violations that needed be addressed to ensure compliance with the law.

116. Plaintiff continued to assiduously correct the many violations and to implement the Lab Operations conformance standards.

117. Not correcting these critical violations would have been illegal and it would have violated the Consent Decree, Federal regulations 21 CFR Parts 210, 211, and 600, the Barr Mandate, and the EU quality regulations.

118. Plaintiff was able to correct, however, the lab operations violations left



129. PIPs, which are issued to individuals who do not meet performance expectations, deadlines.

128. Then in further retaliation, Corcoran unjustly placed Plaintiff on a "Performance Improvement Plan" (hereinafter "PIP"), ostensibly because Plaintiff had missed certain

127. Plaintiff refused to resign.

had missed far more important deadlines, yet they were not being disciplined.

126. Plaintiff said that he was being unfairly targeted and that other Project Managers

125. Plaintiff had not been given any prior warnings.

124. Cybil Robbins laughed in response to this comment.

123. Corcoran mockingly told Plaintiff that he could not speak English clearly.

122. These were the very deadlines that Plaintiff had previously sought to extend.

conformance standards.

he had not met certain intermediate deadlines in implementing the Lab Operations her office, and with Robbins present, tried to force Plaintiff to resign, ostensibly because

121. For example, during the middle of October, 2004, Corcoran called Plaintiff into

Plaintiff.

actions and violations relating to the GMP noncompliance, Defendants retaliated against

120. Because of Plaintiff's ongoing disclosures to his superiors regarding the unlawful

## **DEFENDANTS RETALIATE AGAINST PLAINTIFF**

projects.

119. Plaintiff did so, despite the onerous time constraints and workload with other

Project Managers in Plaintiff's department.

unattended by Robbins within the final deadlines in stark contrast to many of the other

highlight areas where that employee's performance allegedly falls below expectations.

130. Thus the PIP is a final warning pending termination.

131. Upon information and belief, Robbins and the other Caucasian Project Managers were routinely given extensions of deadlines whenever these were requested, and these other Project Managers were not issued with a PIP.

132. Moreover, other Project Managers, as well as Robbins, had missed far more deadlines than Plaintiff, without reasonable grounds, but were not issued with a PIP.

133. Upon information and belief, Plaintiff was the only Project Manager within his Department that had communicated serious violations and unlawful activities.

134. Plaintiff refused to sign the PIP because it was unjust and retaliatory.

135. Other SCI Project managers, including Robbins, Samantha Santoro, Donna Butler, Jackie Flannagan, David Alicandri, Fran Alicata, were not disciplined nor issued PIPs, although they missed far more deadlines.

136. The PIP even falsely indicated that Plaintiff had not told his supervisors that the deadlines needed to be extended.

137. The PIP also set out additional onerous deadlines by which to complete the implementation of the Lab Operations conformance standards.

138. Finally, the PIP falsely indicated that Plaintiff had been previously given six warnings about his work performance and for missing deadlines.

139. On the contrary, prior to this unjustified PIP, Plaintiff had not received any warnings about his work performance.

140. Upon information and belief, WYETH's procedures dictate that written warnings should be issued to an employee prior to issuance of a PIP.

141. The PIP was in retaliation for Plaintiff's complaints and his protected disclosures. 142. Plaintiff was then the subject of further reprisals. 143. For example, Plaintiff was denied the opportunity to attend training in Atlanta in 2004, ostensibly because of the missed deadlines. 144. Plaintiff's peers, however, including Santoro, Alicandri, Alicata, Robbins, attended external training sessions despite having missed more deadlines than Plaintiff. **PLAINTIFF'S FURTHER PROTECTED DISCLOSURES OF NOVEMBER 3, 2004 AND DECEMBER 9, 2004 THAT TRIGGER FURTHER RETALIATION** 145. Plaintiff attempted to have the PIP rescinded, including by email to Hutt dated November 3<sup>rd</sup> 2004. 146. At all relevant times, Hutt was the highest ranking individual in the WYETH Quality organization, and thus ultimately responsible for ensuring compliance with the Lab Operations conformance standards and the Federal regulations in general. 147. In this email, Plaintiff again disclosed the serious violations of Federal regulations, including 21 CFR Parts 210, 211, and 600, and the Barr Mandate, providing the details of each of the violations Plaintiff had to correct to bring WYETH into compliance. 148. The November 3<sup>rd</sup> email was also copied to Louis Fioccola, WYETH's HR representative, Michael B. McDermott, Managing Director at Pearl River, and Christine Wilkinson, the Director of HR. 149. Also, Plaintiff was informed in front of a client that he would not be attending the training on the very day that he was supposed to fly to Atlanta. 150. This was intended to embarrass and humiliate Plaintiff. 151. Despite this action, Plaintiff's work remained exemplary.

152. In spite of the humiliation and stress caused by the retaliatory PIP, by December 8, 2004, Plaintiff had met all deadlines from his 2004 objectives and those deadlines indicated in the PIP, well before the December 31, 2004 deadlines that attached to many of these projects.

153. Plaintiff did so without the benefit of the management support that was given to all his peers, including Robbins, Santoro, Buttler, Alicandri, and Alicata.

154. No other SCI project manager, including Robbins, was able to meet all their 2004 deadlines.

155. In a December 1, 2004 email, Corcoran noted that "8 of 21 goals for November, 2004 were not met," none of the delinquent projects listed in Corcoran's email were Plaintiff's.

156. Also, a report dated December 15, 2004, compiled by Daniel Varas, confirmed that Plaintiff's peers, including Robbins, Alicata, and Alicandri, had all missed a significant number of deadlines.

157. Despite the foregoing, Defendants did not issue any PIP to the other Project Managers in Plaintiff's department.

158. Defendants further damaged Plaintiff's reputation by falsely disparaging his performance in the PIP.

159. Moreover, Robbins conducted one PIP meeting, which was supposed to be confidential, in Plaintiff's office, in full view of his co-workers, thus adding to the humiliation.

160. Defendant Hut and Mike McDermott (Managing Director) had been brought to WYETH Pearl River after the disastrous December 2003 FDA inspection, in which the

FDA issued 59 observations (violations of Federal regulations). 161. They both had a professional and personal financial interest in showing WYETH, the FDA, the EMA, and investors that WYETH Pearl River had changed for the best. 162. The bonuses, performance appraisals, and 2005 compensations of Mr. McDermott, Defendant Hutt, Defendant Corcoran, Robbins, and many other WYETH individuals depended in very significant part in meeting the deadlines that had been given to the FDA

**PLAINTIFF'S FURTHER DISCLOSURES, INCLUDING COMPLAINTS OF VIOLATIONS OF FEDERAL REGULATIONS AND SOX LAW**

163. Meanwhile, Plaintiff continued to make protected disclosures to Defendants. 164. For example, on December 9, 2004, Plaintiff met with Hutt in his office, and, again, disclosed that WYETH was in serious default of the law. 165. During this meeting, Plaintiff highlighted the fact that, in WYETH's implementation of the Lab Operations conformance standards, Plaintiff had uncovered numerous serious violations of 21 CFR 210, 211, and 600, the Consent Decree and the Barr Mandate. 166. That same day, Plaintiff sent Hutt an email in which he reiterated the substance of his conversation with Hutt, stating that "The enclosed file shows the details (with monthly highlights) of the several times I informed Maura and Cybil that the plans Cybil had prepared had to be replaced." 167. On December 15<sup>th</sup> 2004, Plaintiff complained by email to Defendant Hutt and to HR Managers Louis Fioccola and Christine Wilkinson, that he had been the victim of retaliation. 168. In this email, Plaintiff again highlighted the ongoing violations.

169. On January 7, 2005 Plaintiff advised Defendant Hutt, Fiocolla, and Wilkinson, via email, that he believed he was being retaliated against for raising concerns on WYETH's violations.

170. In this email, Plaintiff complained that WYETH retaliated against him for disclosing its violations to his superiors and high level managers.

171. Plaintiff also complained that WYETH's actions violated its "Assurance of Fair Treatment Policy."

172. Plaintiff also highlighted the serious negligence in making Robbins, a non-chemist and a person that had no prior laboratory experience, responsible for implementing the Lab Operations Conformance Standards in the Pearl River facility, especially in light of the Consent Decree and the threat of enforcement action by the EMEA.

173. Defendants never answered this email or otherwise acted upon Plaintiff's complaint.

174. On January 26, 2005, Plaintiff again complained of retaliation to Alex Eslava, and to Mike McDermott, WYETH's Managing Director.

175. From mid December 2004 through mid February 2005 Plaintiff sent more emails complaining of whistleblower retaliation, and in which Plaintiff sought redress and an end to the retaliation and harassment that he was facing.

## **DEFENDANTS RETALIATE BY UNLAWFULLY TERMINATING PLAINTIFF'S EMPLOYMENT**

176. As a result of Plaintiff's protected disclosures and complaints of retaliation, WYETH retaliated by terminating Plaintiff's employment on February 23<sup>rd</sup>, 2004.

177. Plaintiff was discharged on February 23, 2004 during a meeting with

Defendant Corcoran, Christine Wilkinson, and a Human Resource specialist. 178. Plaintiff was not provided with specific grounds for his dismissal, other than vague claims that his employment was terminated because WYETH could not change his behavior.

179. In a further effort to humiliate Plaintiff, he was then made to collect his belongings and escorted out of the building by Human Resources, in full view of his co-workers, at around 1:00 PM when Defendants knew that most of Plaintiff's co-workers would be at their offices.

180. Upon information and belief, WYETH's general practice is to spare employees the humiliation before their peers by communicating termination decisions late in the day or otherwise ask terminates to remain at home.

181. Defendants have persisted in their retaliation and harassment.

182. For example, Plaintiff filed a complaint of retaliation pursuant to SOX with the DOL on March 23, 2005.

183. In response to Plaintiff's complaint of SOX violations to the US Department of Labor, Defendants again falsely disparaged Plaintiff's reputation and character, claiming that he had demeaned his supervisor and co-workers and "generally damaged relationships with key internal clients of his department."

184. These damaging allegations are also false, as Plaintiff always maintained a good working relationship with all his team members, co-workers, and clients.

185. Defendants' actions were intentional and were in retaliation for Plaintiff's protected disclosures and whistleblower activity.

186. Defendants' actions were part of the corporate-wide and department wide pattern

and practice and policy of retaliation against whistleblowers and those employees that complained of retaliation.

187. The actions complained of herein were committed intentionally by Defendants and constitute a continuing policy and practice of retaliation.

188. The individual Defendants aided and abetted WYETH in its retaliatory actions towards Plaintiff and personally directed much of the retaliation.

189. Plaintiff's disclosures were directed at Defendants directly and other high level managers of WYETH.

190. Defendants pressured Plaintiff to ignore WYETH's noncompliance with current Good Manufacturing Practices irrespective of WYETH'S resulting shipment of adulterated product.

191. Defendants' unlawful actions have caused Plaintiff enormous financial hardship and emotional distress.

**COUNT ONE: VIOLATION OF WHISTLEBLOWER PROVISION OF  
SARBANES-OXLEY ACT OF 2002; 18 USC 1514A**

192. Plaintiff repeats the paragraphs of this Complaint as if fully set forth herein.

193. WYETH is a company with a class of securities registered under Section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 781) and is required to file annual reports and quarterly reports for each fiscal year with the Securities and Exchange Commission.

194. The principle executive officer(s) WYETH certify to both the Securities and Exchange Commission and to WYETH's shareholders that all material financial information regarding the company is reported in the annual and quarterly reports.

195. The facts as recited above establish that Plaintiff made numerous protected disclosures as defined by 18 USC 1514A(a).



196. In making these disclosures, Plaintiff reasonably believed that he was reporting violations that are protected pursuant to 18 USC 1514A(a) given that he reasonably believed that he was reporting violations of Federal laws, which regulate the manufacture and release of vaccines in interstate commerce and which prohibit fraudulent reports to the FDA and shareholders.

197. Plaintiff thus reasonably believed that he was reporting violations, which are protected pursuant to 18 USC 1514A(a) against retaliation.

198. Plaintiff directed the protected disclosures to his managers (Robbins and Defendant Corcoran), to the top ranking WYETH individual in the Quality organization at Pearl River (Defendant Hutt), to the Pearl River Managing Director (Michael McDermott), to the top ranking Human Resource individual at Pearl River (Christine Wilkinson).

199. In addition, in making these disclosures, Plaintiff simultaneously invoked the protection of WYETH's Assurance of Fair Treatment Policy, which ostensibly protects whistleblowers from retaliation.

200. Defendants knew the information reported to them by Plaintiff involved a violation of Federal law that related to WYETH's reporting obligations under the Securities and Exchange Act of 1934.

201. Plaintiff's information may have required WYETH to make adverse disclosures to shareholders and the Securities and Exchange Commission in WYETH'S quarterly and annual reports.

202. Plaintiff's disclosures were a "contributing factor" in the adverse personnel actions he suffered. (18 USC 1514A (b)(2)(C)).

- lost health and retirement benefits.
2. Back pay with interest from his date of termination, including compensation for expected in the interim.
  1. Reinstatement to the position that Plaintiff would have occupied but for his unlawful discharge, or, by Plaintiff's agreement, an equivalent position, taking into account the promotions and raises that Plaintiff could reasonably have expected in the interim.
- Wherefore, Plaintiff requests the following relief be granted from Defendants:

### **REQUEST FOR RELIEF**

- unlawful retaliation and harassment under 18 U.S.C. §1514A(a)(1).
208. Plaintiff suffered damages as a result of Defendants Hutt, Corcoran and Robbins' information provided to WYETH that was protected under 18 U.S.C. §1514A(a)(1). constituted unlawful retaliation and harassment against Plaintiff on the grounds of
207. Hutt, Corcoran's and Robbins' adverse employment actions against Plaintiff employment.
- acting as an agent and employee for WYETH when they terminated Plaintiff's
206. Defendants Hutt, Corcoran and Robbins violated 18 U.S.C. §1514A(a)(1) by this paragraph as if fully set forth herein.
205. Plaintiff adopts and incorporates the preceding paragraphs of this Complaint into

### **COUNT TWO: HUTT, CORCORAN'S AND ROBBINS SARBANES-OXLEY VIOLATIONS**

- and/or suspected violations.
- provided the information to his supervisor's regarding ongoing regulatory violations
204. Defendants would not have taken the same actions adverse to Plaintiff had he not disclosures made by Plaintiff during the period June 2004 through his termination.
203. Plaintiff was discharged by Defendants as a direct and proximate result of the

3. Fully restored benefits and seniority rights.
4. Record correction, including expunging Plaintiff's PIP and any other negative records concerning his job performance or qualifications.
5. Compensatory damages for injury to plaintiff, including, but not limited to, injury to his reputation, mental well-being, physical and emotional health, career and income potentials;
6. Front pay;
7. Punitive damages;
8. All other relief which law and equity may provide, including special damages, litigation costs, expert witness fees, and reasonable attorney fees under 18 USC 1514A(c).

**JURY DEMAND**

Plaintiff requests a trial by jury of all issues.

Dated:

April 6, 2006

New York, New York

**MICHAEL SHEN & ASSOCIATES, P.C.**

By:

Ian F. Wallace (LW: 5100)  
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